IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of	:	**Confirmation No. 5973**
Burrhus LANG et al.	:	Attorney Docket No. 2008_0518
Serial No.10/030,519	:	Group Art Unit 3766
Filed June 5, 2002	:	Examiner Mark Bockelman
MEDICAL ELECTRODE	:	**Mail Stop: Appeal Brief-Patents**

APPEAL BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The following is Appellants' brief on appeal of the rejection of April 10, 2007.

REAL PARTY IN INTEREST

The real party in interest in this application is Leonard Lang KG of Innsbruck, Austria.

RELATED APPEALS AND INTERFERENCES

There are no known related appeals and interferences.

STATUS OF CLAIMS

Claims 1-15 and 18 have been canceled.

Claims 16-17 and 19-36 are pending in the application and stand as rejected.

Appeal is taken from the rejection of all of claims 16-17 and 19-36.

STATUS OF AMENDMENTS

No amendments have been filed subsequent to the Office Action of April 10, 2007 or subsequent to the close of prosecution.

SUMMARY OF CLAIMED SUBJECT MATTER

Independent Claim 16

The invention is directed to a medical electrode that has at least one electrically contactable conductor surface that is provided with a connecting bar. Note page 1 of the English language translation of the International Application, lines 5-8. As discussed from lines 9-22, such electrodes are applied to the skin of a patient for a variety of purposes, including monitoring bioelectrical processes of the body or introducing currents into or taking currents from the body.

In order to improve the apportioning of current, in particular in the case of neutral electrodes, and to make such apportioning more uniform, the present invention provides at least one uncontacted conductor surface arranged at a spacing and electrically separated from the at least one electrically contactable conductor surface. See page 2, lines 5-10.

Figure 1 shows a medical skin electrode including a carrier 2 that has two electrically separate conductor surfaces 1a and 1b with respective connecting elements 3. See page 4, lines 11-13.

Fig. 4 illustrates an electrode including two electrically contacted conductor surfaces 1a and 1b and two uncontacted rings 4 and 5 which do not have any connecting elements 3 for an electrode cable. See page 5, lines 12-17 of the specification. As can be seen from Fig. 4, both conductor surfaces 1a and 1b have respective connecting elements 3 for an electrode cable. As discussed beginning at line 20 of page 5 of the specification, the purpose of the uncontacted conductor surfaces or rings 4 and 5 is to achieve uniform current apportionment. Tests on a patient with neutral electrodes have shown that the use of such uncontacted rings involves a substantially lower level of thermal loading by virtue of improved current density distribution. The uncontacted rings and the contacted conductor surfaces 1a and 1b will be arranged on a carrier (not shown in Fig. 4). See lines 25 and 26 of page 5.

Independent Claim 33

Claim 33 is directed to a method of equalizing current in a medical electrode. See page 2 of the specification beginning at line 18, where it is noted that the aim of the uncoated conductor surfaces is to improve current apportionment, in particular in the case of neutral electrodes which take off current, and to make it more uniform.

As noted in the discussion of the electrode of Fig. 4, page 5, beginning at line 12, an electrically contactable conductor surface is provided with a connecting element 3. Further, at least one uncontacted conductor surface is arranged at a spacing from the at least one electrically contactable conductor surface, and the uncontacted conductor surface is free from connecting elements. See also lines 14-17 of page 5; and lines 5-10 of page 2.

Circuitry is connected that delivers to or monitors energy from at least one electrically contactable conductor. Note the discussion at lines 8-12 of page 1; lines 23-28 of page 1; lines 18-26 of page 2; lines 22-25 of page 3; lines 24-29 of page 4, discussing a monitoring apparatus being connected; and line 31 on page 4 to line 2 of page 5, discussing energy transmission in general terms.

The uncontacted surface is electrically unconnected to the circuitry, as it is provided with no connecting elements. See lines 11-17 of page 2.

Energy is delivered to or received from the circuitry via the at least one electrically contactable conductor; see again lines 24-30 of page 4, continuing into the paragraph spanning pages 4 and 5 of the specification, for example. A distribution of the current is equalized by the at least one contacted conductor surface. See again lines 11-17 of page 2, lines 5-10 of page 2 and lines 20-24 of page 5.

Independent Claim 36

Independent claim 36 is directed to a medical system that includes circuitry selected from the group consisting of circuitry that monitors biopotentials and circuitry that provides electrical energy to a patient. See the discussion of the connection of a monitoring apparatus at lines 24-30 of page 4. See also the discussion of energy transmission in the paragraph spanning pages 4 and

5 of the specification. See also lines 5-8 of page 1 of the specification; lines 8-12 of the first page of the specification; lines 25-28 of page 1 of the specification.

A medical electrode comprises at least one energy transmission conductor surface, for example surface 1a or 1b, having a connecting element 3 electrically connected to the circuitry. See Fig. 4 and the discussion beginning at line 12 of page 5 of the specification and continuing through line 24 of that same page. Claim 36 also recites at least one current equalizing conductor surface that is not connected to the circuitry, and spaced from the energy transmission conductor surface to improve current density distribution. See again lines 20-24 of page 5 of the specification.

GROUNDS OF REJECTION

1. The first ground of rejection to be reviewed upon appeal is the Examiner's rejection of claims 16-17, 19-20 and 22-36 under 35 U.S.C. §101 as being inoperative and lacking utility.

2. The second ground of rejection to be reviewed upon appeal is the Examiner's rejection of claims 16-17 and 19-36 under the first paragraph of 35 U.S.C. §112 as not being enabled for the invention as claimed.

3. The third ground of rejection to be reviewed upon appeal is the Examiner's rejection of claims 16-17 and 19-35 as being indefinite for the use of a negative limitation.

4. The fourth ground of rejection to be reviewed upon appeal is the Examiner's rejection of claims 16-17, 19-28 and 30-32 as being anticipated by Canadian Patent 1,219,642 to Frize (Frize).

5. The fifth ground of rejection to be reviewed upon appeal is the Examiner's rejection of claims 16-17 and 19-35 as being anticipated by "the elements found in a hardware store" (hardware store).

6. The sixth ground of rejection for review upon appeal is the Examiner's rejection of claim 29 as being either anticipated by or obvious over Frize.

7. The seventh ground of rejection to be reviewed upon appeal is the Examiner's rejection of claim 36 as being unpatentable under 35 U.S.C. §103(a) over Frize.

ARGUMENT

1. Claims 16-17, 19-20 and 22-36 do not Lack Utility Under 35 U.S.C. §101

Claim 16

As noted in MPEP §706.03(a)(II), a rejection on the ground of lack of utility includes the more specific grounds of inoperativeness, involving perpetual motion. This is not the situation in the present application.

MPEP §2107 presents guidelines for examination of applications for compliance with the utility requirement. As noted in portion II of that section, office personnel are to adhere to the procedures in reviewing patent applications for compliance with the "useful invention" ("utility") requirement of 35 U.S.C. 101 and 112, first paragraph. As can be seen from MPEP §2107(II)(B), if applicant has asserted that the claimed invention is useful for any particular practical purpose, i.e. that it has a specific and substantial utility, and such assertion would be considered credible by a person of ordinary skill in the art, the lack of utility rejection should not be imposed. Under the present invention, Appellants clearly have asserted a credible specific and substantial utility. The claimed medical electrode has utility for varying purposes such as monitoring bioelectrical processes of the body or introducing into or taking from the body currents. The Examiner, indeed, has not challenged the asserted utility as not being credible.

Rather, the Examiner's position appears to be that the claims recite insufficient structure to be operative and therefore lack utility. Thus, the Examiner's position appears to be based upon the logic of MPEP §2107.01(II), alleging that the invention is inoperative and therefore not useful. However, as noted in that section of the MPEP, situations where an invention are found to be inoperative and therefore lacking utility are rare, and rejections maintained solely on this ground by a Federal Court are even rarer. Note in particular the quotation from the case of *Brook Tree Corp. v. Advanced Microdevices, Inc.*, 977 F.2d 1555, 1571, 24 USPQ2d 1401, 1412 (Fed. Cir. 1992). In that case the Federal Circuit stated that "to violate 101 the claimed device must be

totally incapable of achieving a useful result." This is clearly not the case with the present invention.

Independent claim 16 is directed to a medical electrode, which it is submitted has been established by the prior art to have clear utility by itself. The recited elements of the at least one electrically contactable conductor surface provided with a connecting element, and the at least one uncontacted current-equalizing conductor surface arranged at a spacing and electrically separated from the at least one electrically contactable conductor surface, being free from connecting elements, are recited as the elements that are appropriate toward providing the advantages of the invention. As noted at lines 5-10 of page 2 of the specification, in accordance with the invention, at least one uncontacted conductor surface is arranged at a spacing and electrically separated from the at least one electrically contactable conductor surface. This improves current apportionment, as discussed beginning at line 19 on the same page. This represents a clear, credible and substantial utility.

Independent claim 33 recites a method that includes the medical electrode and the above-referenced at least one electrically contactable conductor surface and at least one uncontacted conductor surface. Thus, this claim also has the same clear, credible utility.

Independent claim 36 recites the medical electrode including at least one energy transmission conductor surface having a connecting element and the at least one current equalizing conductor surface spaced from the energy transmission conductor surface to provide improved current density distribution. Thus, the elements recited as part of the medical system of claim 36 also provide a clear and credible utility.

The Declaration under 37 CFR 1.132 submitted by inventor Burrhus LANG further establishes the utility of the present invention. Along with that Declaration was included an article entitled "Numerical Field Calculation of Patient Return Electrodes and Electrosurgery." The Declaration goes on to state that the neutral-ring-bearing electrode that is described in the article, an electrode with a circumferential neutral ring or equipotential ring, is the same electrode that is described and claimed in the present application. The Declaration further goes on to establish that the test results that are referenced in the article establish that an electrode with a

neutral ring significantly reduces heating at the skin surface and exhibits a more symmetrical heating pattern than conventional electrodes.

The Examiner's rejection states that the invention as claimed defies engineering principles in that the claims merely recite two pieces of metal that may or may not be used as a circuit. However, this is an improper view of the claim language. The claim is directed to a medical electrode, which is discussed in the specification as having a clear and credible utility. This is sufficient by itself for purposes of 35 U.S.C. §101.

However, the claim goes on to state that the medical electrode includes at least one electrically contactable conductor surface that is provided with a connecting element. As discussed in the specification, the connecting element is used to connect the medical electrode to outside equipment. There is an addition at least one uncontacted current equalizing conductor surface that is arranged at a spacing and that is electrically separated from the at least one electrically contactable conductor surface, and that, further, is free from connecting elements. Thus, the claim requires an electrode, it requires a conductor surface, it requires a connecting element provided with the conductor surface, and it requires a further current-equalizing conductor surface that is spaced and electrically separated from the electrically contactable conductor surface. Further, the current-equalizing conductor surface must be free from connecting elements. This is a specific recitation of structural components that result in a medical electrode that has the utility that is described in the specification.

The Examiner's statement that the "two pieces of metal" may or may not be used as a circuit is inapt. It does not relate to the requirements of 35 U.S.C. §101. In any case, what is claimed is a medical electrode in the case of claim 16. The Examiner's statement that Appellant claims nothing more than two pieces of metal is clearly incorrect; the claim requires a medical electrode, including an electrically contactable conductor surface, a connecting element, and an uncontacted current-equalizing conductor surface that is spaced and electrically separated from the contactable conductor surface, and free from a connecting element.

The Examiner's further conclusion, that Appellants need to recite the "contactless" electrode to be a ring, essentially fully surrounding the inner electrode for it to be operable, is

incorrect and unsupported by evidence. The Examiner is substituting the Examiner's opinion for the evidence of record. As is reflected in the above-cited portions of the MPEP, a rejection under 35 U.S.C. §101 is inappropriate under these circumstances. (The Examiner's rejection appears almost to be more concerned with the breadth of the language of the claims in requiring the recitation of a ring shape. However, applicants are generally free express the invention in appropriate terms of their choice. It is noted that the claims require the uncontacted electrode to be a current-equalizing conductor surface that is electrically spaced and separated from the contactable conductor surface. This is the choice of language, perhaps different from what the Examiner would prefer, which nonetheless expresses the function and structure required for operability.)

As a general matter, the inoperability standard for utility applies primarily to claims with impossible limitations. *CFMT, Inc. v. Yield Up International Corp.*, 349 F.3d 1333, 1339, 68 USPQ2d 1940 (Fed. Cir. 2003). Also, where a patent discloses several alternative combinations of methods, as most system claims will, a party asserting inoperability must show that all disclosed alternatives are inoperative or not enabled. *EMI Group North America, Inc. v. Cypress Semiconductor Corp.*, 268 F.3d 1342, 1348, 60 USPQ2d 1423 (Fed. Cir. 2001). Also note *Carl Zeiss Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1181 n.5, 20 USPQ2d 1094, 1101 n.5 (Fed. Cir. 1991): a patent claim was not invalid for lack of utility in failing to describe an inoperable device; subcombination claiming is consistent with the utility requirement in section 101, so long as what is described in the claims has utility in itself. The fact that an invention is only of limited utility and is only operable in certain applications is not grounds for finding of a lack of utility. See *Envirorotech Corp. v. Al George Inc.*, 730 F.2d, 1753, 221 USPQ 473 (Fed. Cir. 1984).

Before the Patent Office, an invention is presumed to be operable as disclosed. The burden of providing operability and utility shifts to the Appellant only if there is a reasonable doubt as to the truth of the Appellant's assertions. The Examiner's assertions in this case do not raise a reasonable doubt. Further, any doubt under the present circumstances has been rebutted by the Declaration by Burrhus LANG that establishes the operability of at least one embodiment of the specification.

The Patent and Trademark Office examination guidelines for the utility requirement state that where a mode of operation is readily understood and conforms to the known laws of physics and chemistry, operativeness is not questioned, and no further evidence is required. On the other hand, if the alleged operation seems clearly to conflict with a recognized scientific principle, as for example where an Appellant purports that the discovered machine produces perpetual motion, the presumption of inoperativeness is so strong that very clear evidence is required to overcome it. A third situation is where a device is of such a nature that it cannot be tested by known scientific principles. In this case it is incumbent upon the Appellant to demonstrate the workability and utility of the device and to make clear the principles on which it operates.

In the present situation, while it is not believed to represent the third situation above, Appellants have in any case demonstrated the operability of at least one embodiment of the invention through the Declaration of Burrhus LANG.

It is respectfully submitted that the Examiner's rejection of the invention of claims 16, 33 and 36, as well as all of the dependent claims, under 35 U.S.C. §101 is insufficient as a matter of law and inappropriate under the present circumstances. Reversal of the rejection is accordingly requested.

Claim 19

Claim 19 further requires that the at least one electrically contactable conductor surface and the uncontacted conductor surface are arranged on a common carrier. This additional limitation further establishes the operative utility of the claimed arrangement in that the conductor surfaces are required in the claim to be on a common carrier in their electrically separated and spaced relationship.

Claim 20

This claim further requires that the current-equalizing uncontacted conductor surface at least partially surround one or more contacted conductor surfaces or extend along the same. Thus, this claim includes further structure that in one way relates to the operation of the device.

Claim 21

The Examiner's implicit requirement that the uncontacted conductor surface should be claimed as a circular ring is met by claim 21, and thus the Examiner's rejection does not appear to be applicable to claim 21.

Claim 22

This claim further requires that the uncontacted conductor surface extend into an intermediate space that is between two spaced contacted conductor surfaces or into a recess configuration. This limitation further relates to the relationship between the two conductor surfaces and further supports the operative utility of the invention.

Claim 23

Claim 23 further recites that there are two uncontacted conductor portions that are curved and parallel, which arrangement relates to the operation of the device and further supports the operative utility of the invention.

Claim 33

In addition to the above arguments relating to claim 16, the following is noted regarding claim 33. Claim 33 is a method claim that includes the steps of providing a medical electrode, connecting circuitry with the electrically contactable conductor of the electrode and delivering to or monitoring energy from the electrically contactable conductor, leaving the uncontacted surface electrically unconnected to the circuitry, and delivering to or receiving an energy transmission from the circuitry to the at least one electrically contactable conductor. Further, the claim requires equalizing the distribution of the current with the at least one uncontacted conductor surface. According to the terms of the specification, this method clearly has operative utility. Such is in fact emphasized in the claim by reciting the equalization of the distribution of the current with the at least one uncontacted conductor surface. In any case, as also discussed above,

the utility requirement is not so narrow, and it is submitted to be clear that the method claim has utility for purposes of 35 U.S.C. §101 on its face.

Claim 34

Claim 34 further requires that the electrically contactable conductor surface and the uncontacted conductor surface are arranged on a common carrier. This further emphasizes the operative arrangement according to an embodiment of the present invention.

Claim 35

This claim further requires that the uncontacted conductor surface at least partially surround the contacted conductor surface. This also emphasizes the nature of the operation of the present invention in one or more of the disclosed embodiments. As such, this claim further supports the utility of the invention.

Claim 36

Claim 36 recites the medical electrode including the at least one energy transmission conductor surface having a connecting element that is electrically connected to circuitry. There is also at least one current equalizing conductor surface that is not connected to the circuitry. The at least one current equalizing conductor surface is spaced from the energy transmission conductor surface to provide improved current density distribution.

Accordingly, it is seen that the language of claim 36, in reciting a medical system that includes not only the circuitry that monitors biopotentials or provides electrically energy to a patient, but also the medical electrode, reflects the operative utility in requiring that the current equalizing conductor surface is spaced from the energy transmission conductor surface to provide improved current density distribution. This utility is supported by the specification, and as such the claim clearly has utility under 35 U.S.C. §101 on its face.

2. Claims 16-17 and 19-36 are Enabled

Claim 16

The Examiner's rejection of the claims as not being enabled states that the specification enables an arrangement shown in a Reiser et al. patent but does not enable the invention in a manner commensurate in scope with the claims. The Examiner states that Appellants' claims seem to require, at a minimum, a ring surrounding an electrode. The Examiner's position fundamentally misunderstands the requirements of 35 U.S.C. §112, first paragraph.

As set forth in MPEP §2164.01, the test for enablement is whether one reasonably skilled in the art could make or use the invention from the disclosure in the patent coupled with information known in the art without undue experimentation. Thus, some experimentation is permitted as long as such experimentation is not undue.

As set forth in MPEP §2164.01(a), there are a number of factors to be considered, including the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill in the art, the level of predictability in the art, the amount of direction that is provided by the inventor in the specification, the existence of working examples and the amount of experimentation that would be needed to make or use the invention based upon the content of the disclosure. In the present circumstances, the Examiner's attention seems to be clearly focused solely on the breadth of the claims.

However, it is noted that each of the independent claims recites a medical electrode, rather than the Examiner's mis-characterization of the claims as reciting just two pieces of metal. The components of the medical electrode are specified and include at least one electrically contactable conductor surface provided with a connecting element. The medical electrode is further provided with at least one uncontacted current-equalizing conductor surface. Thus, the claims reflect the fact that the purpose of the uncontacted conductor surface is to equalize the current in the contactable conductor surface. Its purpose is emphasized by the fact that it is recited as being arranged at a spacing and electrically separated from the at least one electrically contactable conductor surface. Further, it is free from connecting elements, which emphasizes

the fact that it is not provided with or conducts energy. Rather, its purpose is to equalize the current in the contacted conductor surface.

Thus, the breadth of the claims is not so broad as to represent simply two pieces of metal as the Examiner states.

The nature of the invention is a medical electrode, which in the art, largely, are relatively straight forward electro-mechanical devices. The state of the prior art includes existing neutral electrodes which have at least two electrically separate conductor surfaces wherein an electronic evaluation device individually monitors the currents that are taken from the respective conductor surfaces. Note the background of the invention on page 1 of the original English language translation. The specification recognizes on page 2 that a gap between the rectangular conductor surfaces of the known neutral electrode must be precisely oriented with respect to an area of operation, otherwise the two conductor surfaces are supplied differently with current. As further described beginning at line 5 of page 2 of the specification, it is for this reason that the present invention has been developed.

As discussed beginning at line 11 of page 2, a ring surrounding an electrode, as required by the Examiner to achieve an enabled claim, is an example given by the present specification. The same paragraph on page 2 of the specification provides several alternatives to the circular ring.

The same page of the specification describes a preferred embodiment which has one conductor surface at least partially surrounding another conductor surface. As can be seen from the drawing figures, the uncontacted conductor surfaces can include rings 4 and 5. However, it is a relatively simple matter for one of ordinary skill in the art to imagine different arrangements of uncontacted conductor surfaces to be arranged and spaced from the contacted conductor surfaces so as to equalize the current but without necessarily requiring a ring shape. The breadth of Appellants' claims should not be limited by exemplary embodiments in a situation where one of ordinary skill in the art readily recognizes that other arrangements will achieve the same function of equalizing a current by appropriate spacing and arrangement to do so.

The art of this application is not so new or unpredictable that Appellants' claim should be strictly limited to the working examples that are disclosed. A broader scope of protection should be permitted in this type of art. As noted in MPEP §2164.03, the amount of guidance or direction that is needed to enable an invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art.

As noted in MPEP §2164.04, the Examiner's burden is to establish a reasonable basis to question the enablement provided for the claimed invention. This requires a reasonable explanation as to why the scope of protection is not adequately enabled. In the present situation, however, the Examiner has simply stated that the claims require a ring surrounding an electrode. However, the Examiner provides no analysis or discussion of why anything else should be required in this particular art.

From the above it is respectfully submitted to be clear that the Examiner has failed to establish a *prima facie* case of a lack of enablement of independent claim 16. Reversal of this rejection is accordingly requested.

Claims 20-23

Claim 20 further requires that the uncontacted conductor surface at least partially surround one or more contacted conductor surface or extend along them. This structure relates to the operation of the embodiment and its structure which is clearly enabled by the specification. Further, to the extent that the Examiner believes that there should be more limitations in the claims, claim 20 satisfies this requirement.

The same essential point is true for claims 21, 22 and 23.

Claim 33

Claim 33 is a method of equalizing the current. One of the steps is the provision of a medical electrode, which is fully enabled, as discussed above.

Further, all of the method steps are clearly enabled by the specification as presented. There is sufficient discussion in the specification to enable one of ordinary skill in the art to employ the method without undue experimentation.

Claim 34 and Claim 35

Both of these claims recite further structure relating to the uncontacted conductor surface relating to the operation of the invention and in effect satisfying the Examiner's requirements.

Claim 36

Claim 36 relates to a medical system that includes circuitry and a medical electrode. This claim is also fully enabled by the specification for the same reasons as set forth above with respect to claim 16.

3. Independent Claims 16-35 are Definite

The Examiner has rejected claims 16-35 as being indefinite for using the word "uncontacted." This is considered by the Examiner to be a negative limitation. In support of the argument, the Examiner states that any metal surface can be used as a contact, or not.

However, the use of a negative limitation is not per se indefinite. MPEP §2173.05(i). So long as the boundaries of the patent protection sought are definitely set forth, even if negatively, the claim complies with the requirements of 35 U.S.C. §112, second paragraph. Note the example given in the second paragraph of that section of the MPEP. "A claim which recited the limitation of 'said homopolymer being free from the proteins, soaps, resins and sugars present in natural Hevea rubber' in order to exclude the characteristics of the prior art product, was considered definite because each recited limitation was definite." This is very similar to the present circumstances.

Independent claim 16 recites that the at least one uncontacted current-equalizer connector surface is "free from connecting elements." Claim 33 recites that the medical electrode has at least one uncontacted conductor surface "which is free from connecting elements." Both claims

make it clear that the uncontacted conductor surface is free from connecting elements. One of ordinary skill in the art readily understands what is meant in this situation. That is, it is readily understood that there is no connecting element to connect the conductor surface to other circuitry. While the Examiner's statement that any metal surface can be used as a contact or not might be correct, this is not the point. The point is that the specification is reciting an arrangement of parts in which one of the elements, which may be a metal surface, is uncontacted, which is defined as being free from connecting elements. Particularly in view of the specification, this limitation is clearly understood in the context of circuitry. That is, one of ordinary skill in the art would readily be able to recognize whether a potentially infringing product had a conductor surface arranged with a connecting element, or not.

4. Claims 16-28 and 30-32 are not Anticipated by Canadian Patent 1,219,642

Claim 16

Claim 16 requires at least one uncontacted current-equalizing conductor surface arranged at a spacing and electrically separated from at least one electrically contactable conductor surface, which uncontacted current-equalizing conductor surface is free from conducting elements. There is no such uncontacted current-equalizing conductor surface in Frize, the Canadian patent.

The Examiner makes reference to Fig. 3 of Frize, which includes electrode elements 30, 33 and 36. As described in Frize, each extends to a connector tab 32 by way of connector links 31, 35 and 38. Frize has no conductor surfaces free from connecting elements.

The Examiner takes the position that the elements are each capable of being contactable by an electrode or can be considered free of a contacting element depending upon the intended use. The Examiner notes that Appellants' circular rings are shown in their drawings as all being capable of being contacted by an electrical energy applicator. The Examiner thus designates which elements are contactable in terms of intended use in interpreting Appellants' claims. However, this position by the Examiner is contrary to law and must be reversed.

As described in the specification and reflected in independent claim 16, the point of the invention is that a medical electrode has at least one electrically contactable conductor surface that is provided with at least one uncontacted current-equalizing conductor surface for the purpose of equalizing the current provided to the contactable conductor surface. It is arranged at a spacing and is electrically separated from the at least one electrically contactable conductor surface. Further, it is free from connecting elements.

In the Canadian patent to Frize, as described beginning at line 5 of page 3, an electrode for connection to an electrosurgical generator comprises a plurality of separate conductive elements that are spaced apart in a surface plane and attached to a non-conductive backing. A connector is provided from each one of the conductive elements to a resistor having a resistance value that is proportional to the current flow through the one of the conductive elements is provided for uniform current distribution. As is appreciated from the general description of Frize, as well as the drawings thereof, each conductor surface has a respective connecting element and corresponding resistor.

The Examiner cannot designate contacts of Frize as being free of a contacting element depending upon the intended use. The intended use for each of the conductor surfaces in Frize is to be connected with a connecting element, as illustrated, through a resistor. The Examiner's position appears to be saying that the Examiner is free to ignore structural features that Frize clearly provides. However, any such interpretation is impermissible.

Appellants circular rings being capable of being contacted by an electrical energy applicator is irrelevant. The point is that they are not contacted, which is what is claimed.

Appellants provide an embodiment in Fig. 4, for example, in which there are two contactable conductor surfaces 3 and two uncontacted current-equalizing conductor surfaces 4 and 5 that are free from connecting elements. Are they somehow capable of being contacted by an electrical energy applicator if someone decided to contact them? That is an irrelevant point, because that is not what is being claimed. What is being claimed is that they are free from connecting elements, which the conductor surfaces of Frize are not. There is a reason they are

free from connecting elements in the present invention, which is to use these conductor surfaces as current-equalizing conductor surfaces. Frize specifically wants the connection.

Simply stated, Frize doesn't have the claimed structure. It is legally insufficient to say that Frize could have the claimed stricture if you change the meaning of the claim language. The language in fact requires that the uncontacted connector be free from a connecting element. This is not a statement of intended use but a structural requirement.

The differences between the present invention and Frize are emphasized by the recitation of the current-equalizing conductor surfaces being free from connecting elements, while the contactable conductor surface has a connecting element. One of ordinary skill in the art clearly understands what is a connector element in the context of an electrode. The Examiner is not free to ignore structural features or a required absence of a structural feature, particularly when it directly relates to the purpose of the invention.

The Examiner's position with respect to anticipation of claim 16 is clearly improper, and the rejection must be reversed.

Claim 19

Claim 19 emphasizes that the uncontacted conductor surface, as well as the contactable conductor surface, are arranged in a common carrier. While all of the electrodes of Frize appear to be on a common carrier, there is no uncontacted conductor surface on the common carrier.

Claim 20

Claim 20 further requires that the uncontacted conductor surface, which is free from connecting elements as recited in claim 16, at least partially surrounds one or more contacted conductor surfaces or extends along the same. While Frize has conductor surfaces that at least partially surround or extend along other conductor surfaces, it has no uncontacted conductor surfaces that at least partially surround or extend along a contacted conducted surface.

Claim 21

Claim 21 requires that the uncontacted conductor surface is shaped as a circular ring. There is no uncontacted conductor surface in Frize shaped as a circular ring.

Claim 22

Claim 22 further requires that the uncontacted conductor surface, which is free from connecting elements, extends into an intermediate space between two spaced contacted conductor surfaces, or into a recess configuration and a conductor surface. There is no structure in Frize in which there is an uncontacted conductor surface that extends into an intermediate space between two spaced conductor surfaces or into a recess configuration in a conductor surface.

Claim 23

Claim 23 further requires that are two uncontacted conductor portions, which are free from connecting elements, and which are parallel. There are no such features in Frize.

Claim 33

Claim 33 is a method of equalizing current in a medical electrode. The first step of this method is to provide a medical electrode that has at least one electrically contactable conductor surface that is provided with a connecting element and have at least one uncontacted conductor surface that is arranged at a spacing from the at least one electrically contactable connector surface and that is free from connecting elements. As was discussed above with respect to claim 16, Frize has no such uncontacted conductor surface that is free from connecting elements.

While Frize does connect circuitry to deliver or monitor energy from at least one electrically contactable conductor, Frize does not leave an uncontacted surface electrically unconnected to the circuitry. There is no such discussion in Frize and no indication from Frize that any conductor surface should be left uncontacted.

Claim 33 further requires that an energy transmission should be delivered to or received from the circuitry to the at least one electrically contactable conductor and that the at least one uncontacted conductor surface equalize the distribution of the current. There is no equalization of the distribution of the current using an uncontacted conductor surface in Frize. Rather, Frize uses resistors for this purpose.

Accordingly, it is respectfully submitted to be clear that Frize fails to provide all of the steps that are provided in method claim 33, and does not anticipate the claim. Reversal of this rejection is further requested.

The Examiner states that the method step would be inherent since the method does not require the uncontacted metal surface to remain unconnected to the electrical stimulator. However, claim 33 requires that the distribution of the current be equalized with the at least one uncontacted conductor surface. Further, claim 33 requires the step of leaving the uncontacted surface electrically unconnected to the circuitry. Thus, the Examiner's statement that the method does not require the uncontacted metal surface to remain unconnected is clearly incorrect. The claim in fact clearly states this. Further, the claim further requires the equalization of the distribution of the current using the uncontacted conductor surface, which does not take place in Frize. This is not an inherent feature of Frize, as current, to the extent that it is equalized in Frize, is equalized using the resistors.

Claim 34

As discussed above, Frize further does not have the at least one electrically contactable conductor surface and the at least one uncontacted conductor surface arranged in a common carrier, because there is no uncontacted conductor surface in Frize.

Claim 35

Claim 35 requires that the step of providing the medical electrode include providing the at least one uncontacted conductor surface to at least partially surround one or more contacted

conductor surfaces or extend along the same. Frize has no step of providing a medical electrode with an uncontacted conductor surface, and cannot meet this limitation, accordingly.

Claim 36

Claim 36 requires a medical system that includes circuitry that is selected from the group consisting of circuitry that monitors biopotentials and circuitry that provides electrical energy to a patient. The medical system further requires a medical electrode including at least one energy transmission conductor surface that has a connecting element that is electrically connected to the circuitry. Claim 36 further requires at least one current equalizing conductor surface that is not connected to the circuitry. The at least one current equalizing conductor surface is required to be spaced from the energy transmission conductor surface to provide improved current density distribution. These elements are not met by Frize.

In Frize, as discussed above, there are a plurality of conductor surfaces. However, all of the conductor surfaces are connected to circuitry in use. Note Fig. 2 for example. Thus, Frize provides no medical system in which a medical electrode has an energy transmission conductor that is electrically connected to the circuitry and a current equalizing conductor surface that is not connected to the circuitry.

5. Claims 16-35 are not Anticipated by a Hardware Store

In this rejection, the Examiner takes the position that the claims are anticipated by elements that can be found in a hardware store. The Examiner states that the two pieces of metal that Appellants recite can be found in any hardware store. This apparently includes washers, slugs, eyehook hangers of different sizes, etc. The Examiner states that each of these sets of elements are capable of being arranged in the configuration that has been claimed. For example, two mounting hooks of different sizes could be arranged to one within the other. Slugs and washers could also be arranged in this manner. This position by the Examiner, however, seriously misunderstands what is required to anticipate the elements of a claim. This rejection manifestly fails to present a *prima facie* case of anticipation.

Claim 16

Claim 16 requires a medical electrode. The Examiner has cited nothing from a hardware store that would be recognized by one of ordinary skill in the art to correspond to a medical electrode. For this reason alone, it is respectfully submitted that the Examiner's rejection fails.

The medical electrode of claim 16 further requires at least one electrically contacted conductor surface that is provided with a connecting element. The Examiner has cited no conductor surfaces that have a connecting element.

The claim further requires at least one uncontacted current-equalizing conductor surface which is arranged at a spacing and electrically separated from the at least one electrically contactable conductor surface. The manner of recitation of the uncontacted current-equalizing conductor surface requires a particular relationship to the contactable conductor surface. That is, it must be spaced and electrically separated from the at least one electrically contactable conductor surface so that it is a current-equalizing conductor surface. Further, it must be free from connecting elements. Further, these elements together must make up a medical electrode.

The Examiner has cited nothing from a hardware store that could meet the limitation of having one conductor surface with a connecting element, another conductor surface that is arranged at a spacing and electrically separated so as to provide a current-equalizing conductor surface and that is free from connecting elements.

The Examiner's position that elements that can be found in a hardware store are capable of being in a configuration as claimed by Appellants fails to meet the requirements for anticipation. Any combination invention could be said to be anticipated if all that is required is that the various elements of the combination be found somewhere. This is in fact the case for practically any combination invention in the electrical or mechanical arts, as practically all of the parts are already in existence. It is the arrangement of those parts with respect to each other, as for example in claim 16, that is the point. Thus, the Examiner's statement misunderstands what is required for anticipation. This rejection fails to present a *prima facie* case of anticipation of claim 16, and the rejection must be reversed.

Claim 17

Claim 17 requires that the connecting element be a tab. The Examiner's reference to a hardware store indicates no such structural feature.

Claim 20

This claim requires that the uncontacted conductor surface at least partially surround one or more contacted conductor surfaces or extend along the same. This feature is not found in the hardware store cited by the Examiner.

Claim 22

This claim requires that the uncontacted conductor surface extend into an intermediate space between two spaced contacted conductor surfaces or into a recess configuration of a conductor surface. There is no such structure found in the hardware store cited by the Examiner.

Claim 23

This claim requires that two uncontacted conductor portions be curved parallel. There is no indication from the hardware store that two uncontacted conductor portions would be curved parallel.

Claim 24

This claim requires that there be at least two electrically separated contactable conductor surfaces with one of the conductor surfaces at least partially surrounding another of the conductor surfaces. There is nothing in the hardware store cited by the Examiner to meet this limitation.

Claim 25

This claim requires an inner conductor surface be surrounded by an outer conductor surface that extends around the inner conductor surface at a constant gap spacing relative to the outer edge thereof. Even if the hardware store cited by the Examiner has an inner and outer

conductor surface, there is nothing to indicate that they would be provided at a constant gap spacing as required.

Claim 26

This claim requires that an inner conductor surface be of a substantially round circular configuration which is surrounded by an outer conductor surface in the form of a circular ring. The Examiner's reference to a hardware store provides no such structure.

Claim 27

This claim requires that the outer conductor surface surround the inner over an angular range of more than 270°. There is no structure cited by the Examiner's hardware store that meets this limitation.

Claim 28

This claim requires that an inner conductor surface and an outer conductor surface surrounding the inner conductor surface have respective projecting connecting elements for an electrode cable, the connecting elements being arranged laterally one beside the other and parallel to each other. There is nothing from the Examiner's reference to a hardware store that meets this limitation.

Claim 29

This claim requires two electrically contactable conductor surfaces that are in different radial positions while the surface areas and the peripheral lengths thereof are substantially equal. There is nothing from the Examiner's reference to a hardware store that meets this limitation.

Claim 30

This claim requires that the at least one conductor surface have a hook shape that surrounds the other conductor surface. There is nothing from the Examiner's reference to a hardware store that meets this limitation.

Claim 31

This claim requires that each conductor surface have a hook-shape projection interleaved one into the other. There is nothing from the Examiner's reference to a hardware store that meets this limitation.

Claim 33

As discussed above, claim 33 is directed to a method of equalizing the current in a medical electrode. The Examiner's reference to a hardware store is completely devoid of any method of equalizing the current in a medical electrode. The reference to a hardware store clearly fails to meet the limitations of any of the steps that are set forth in claim 33.

For example, the first step is that of providing a medical electrode. The Examiner has not provided a medical electrode in referencing a hardware store.

The second step is to connect circuitry that delivers to or monitors energy from the at least one electrically contactable conductor. The reference to a hardware store is devoid of connecting any circuitry.

The same is true for the further steps of leaving, delivering or receiving, and equalizing, as recited in claim 33.

Claim 35

This claim further requires providing the medical electrode with the at least one uncontacted conductor surface at least partially surrounding one or more contacted conductor surfaces or extending along the same. This is clearly not found in the Examiner's reference to a hardware store.

Claim 36

The Examiner did not reference claim 36 in rejecting the claims based upon the elements found in a hardware store, and no further distinction is thus deemed to be necessary.

6. Claim 29 Clearly Distinguishes Over Frize

Claim 29 requires two electrically contactable conductor surfaces at different radial positions, with the surface areas and their peripheral lengths being substantially equal. The Examiner considers the hook configurations of the various conductors in Fig. 4 of Frize, the Canadian reference, to substantially equal surface areas and peripheral lengths, or it would have been obvious to modify them to be within a range of being substantially equal as an obvious design choice. However, this position by the Examiner is unsupported by Frize.

Frize provides no indication of surface areas and peripheral lengths of contactable conductor surfaces at different radial positions being substantially equal. In fact, looking at the drawing figures, the surface areas and peripheral lengths clearly appear to be different.

Further, there is no evidence of record that this amounts to an obvious design choice to one of ordinary skill in the art.

7. Claim 36 Patentably Defines Over Frize

The Examiner considers claim 36 to read upon an intermediate configuration during the hook up of electrodes to the device of use in Frize. However, this position is respectfully submitted to be incorrect.

Looking at Figs. 1 and 2 of Frize, it can be seen that Frize connects the medical electrode 11 having all of the conductor surfaces 20, 21 and 22 with connecting elements to circuitry through a plug 13. This connects all of the electrodes at the same time. Thus, as a matter of fact, there is no intermediate configuration of Frize during hook up of the electrode to the device where one contact is connected and the other is not connected.

Further, the medical system involves the circuitry being connected to the energy transmission conductor surface through the connecting element, while the current equalizing

conductor surface is not connected. The medical system of Frize does not contemplate any situation in which the conductor surfaces are not connected. Thus there never is a medical system having this arrangement.

CONCLUSION

For the above reasons it is respectfully submitted that all of claims 16-17 and 19-36 represent patentable subject matter having utility, are enabled by the present specification and patentably distinguish over Frize as well as parts found in a hardware store. Reversal of the rejections made by the Examiner is accordingly requested.

Respectfully submitted,

Burrhus LANG et al.

/Nils E. Pedersen/
2008.11.13 16:31:51 -05'00'

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APPENDIX - Claims on Appeal

16. A medical electrode comprising at least one electrically contactable conductor surface provided with a connecting element, and having at least one uncontacted current-equalizing conductor surface which is arranged at a spacing and electrically separated from the at least one electrically contactable conductor surface and which is free from connecting elements.

17. The medical electrode as set forth in claim 16 characterized in that the connecting element is a tab.

19. The medical electrode as set forth in claim 16 characterized in that the at least one electrically contactable conductor surface and the uncontacted conductor surface are arranged on a common carrier.

20. The medical electrode as set forth in claim 16 characterized in that an uncontacted conductor surface at least partially surrounds one or more contacted conductor surfaces or extends along same.

21. The medical electrode as set forth in claim 16 characterized in that the uncontacted conductor surface is shaped as a circular ring.

22. The medical electrode as set forth in claim 16 characterized in that an uncontacted conductor surface extends into the intermediate space between two spaced contacted conductor surfaces or into a recess configuration in a conductor surface.

23. The medical electrode as set forth in claim 16 characterized in that there are provided two uncontacted conductor portions which are curved parallel.

24. The medical electrode as set forth in claim 16 characterized in that there are provided at least two electrically separated contactable conductor surfaces, wherein one of said conductor surfaces at least partially surrounds another of said conductor surfaces.

25. The medical electrode as set forth in claim 24 characterized in that an inner conductor surface is surrounded by an outer conductor surface which extends around the inner conductor surface at a constant gap spacing relative to the outer edge thereof.

26. The medical electrode as set forth in claim 24 characterized in that an inner conductor surface is of a substantially round circular configuration and is surrounded by an outer conductor surface in the form of a circular ring.

27. The medical electrode as set forth in claim 24 characterized in that the outer conductor surface surrounds the inner over an angular range of more than 270°.

28. The medical electrode as set forth in claim 24 characterized in that at least one inner conductor surface and an outer conductor surface surrounding same each have a respective projecting connecting element for an electrode cable, wherein the connecting elements are arranged laterally one beside the other and parallel to each other.

29. The medical electrode as set forth in claim 24 characterized in that there are provided two electrically contactable conductor surfaces in different radial positions, the surface areas and peripheral lengths thereof being substantially equal.

30. The medical electrode as set forth in claim 24 characterized in that at least one conductor surface is of a hook-shaped configuration, the hook surrounding the other conductor surface.

31. The medical electrode as set forth in claim 24 characterized in that each conductor surface has hook-shaped projections which are interleaved one into the other.

32. The medical electrode as set forth in claim 16 characterized in that the outside contour of the conductor surface or surfaces is round.

33. A method of equalizing the current in a medical electrode comprising the steps of:

providing a medical electrode comprising at least one electrically contactable conductor surface provided with a connecting element, and having at least one uncontacted conductor surface which is arranged at a spacing from the at least one electrically contactable conductor surface and which is free from connecting elements;

connecting circuitry that delivers to or monitors energy from at least one electrically contactable conductor;

leaving the uncontacted surface electrically unconnected to said circuitry;

delivering or receiving an energy transmission from said circuitry to the at least one electrically contactable conductor; and,

equalizing the distribution of the current with the at least one uncontacted conductor surface.

34. The method according to claim 33 further comprising providing the medical electrode with the at least one electrically contactable conductor surface and the at least one uncontacted conductor surface arranged on a common carrier.

35. The method according to claim 33 further comprising providing the medical electrode with the at least one uncontacted conductor surface at least partially surrounding one or more contacted conductor surfaces or extending along same.

36. A medical system comprising:

circuitry selected from the group consisting of circuitry that monitors biopotentials and circuitry that provides electrical energy to a patient;

a medical electrode comprising at least one energy transmission conductor surface having a connecting element electrically connected to said circuitry, and at least one current equalizing conductor surface, wherein said current equalizing conductor surface is not connected to said circuitry, said at least one current equalizing conductor surface spaced from said energy transmission conductor surface to provide improved current density distribution.

APPENDIX - Evidence

1. Declaration Under 37 C.F.R. §1.132
2. Article entitled "NUMERICAL FIELD CALCULATION OF PATIENT RETURN ELECTRODES IN ELECTROSURGERY"

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
LANG et al.

Atty. Docket No. TRG-299

Title: Medical Electrode

Serial No.: 10/030,519

Art Unit: 3762

Filed: October 29, 2001

Examiner: Bockelman

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.132

Sir:

I, Burrhus Lang, do hereby declare and say that:

1. I have been an employee of Leonhard Lang KG since 1989. I currently hold the position of Chief Executive Officer (Managing Director) and through my position have specific personal knowledge of all of the company's inventions including all aspects of the invention described and claimed in U.S. Patent Application Serial No. 10/030,519 ("the '519 application), of which I am a named inventor.

2. Leonhard Lang KG manufactures and sells medical electrodes, and is the 100% owner of the '519 application entitled "Medical Electrode." I have acquired considerable expertise in the medical electrode field through my employment with Leonhard Lang.

3. Attached hereto is an article entitled, "NUMERICAL FIELD CALCUTAION OF PATIENT RETURN ELECTODES IN ELECTOSURGERY."

The article was published in "Proceedings of Biomedizinische Technik," Volume 47, Ergänzungsband 1, Teil 1,274-277, 2002. I know one of the co-authors, J. Raiser, who is an employee of a customer that purchases products from Leonhard Lang KG. Leonard Land KG produces electrodes made in accordance with the teachings of the '519 application (electrodes with circumferential neutral rings) and sells them to the customer.

4. I have read the article and can confirm that the neutral-ring-bearing electrode described in the article—an electrode with a "circumferential neutral ring ('equipotential ring')" –is the same electrode described and claimed in the '519 application.

5. The test results referenced in the article clearly establish that an electrode with a neutral ring significantly reduces heating at the skin surface and exhibits a more symmetrical heating pattern (homogeneous heat distribution) than a conventional electrode that lacks a neutral ring. The observed symmetrical heating pattern is the direct result of the neutral ring that equalizes current distribution about the electrode. An electrode having a symmetrical current distribution pattern produces a symmetrical heating pattern when a current is applied to the electrode. I am not aware of any conventional electrodes that produce results similar to those achieved with a neutral-ring-bearing electrode.

6. I have read the specification and pending claims of the '519 application and have a thorough understanding of the claimed invention. I have also reviewed the August 14, 2006 office action as well as Canadian Patent No. 1,218,642.

7. I do not agree with the characterization of the '642 patent in the office action. The '642 patent addresses the problem of asymmetrical heat distribution

produced by an electrode, but does so in a completely different way from that shown, described and claimed in the '519 application. The electrodes described in the '642 patent are consistently described as containing multiple discreet conductive segments, each of which is attached to a resistor to control the amount of current flowing through the conductive segment. The values of the resistors are varied depending on the location of the segment, e.g., center, peripheral, etc., so that the current flow through each segment can be equalized. Support for my position is found at page 2, line 24 ("*each* section being connected to a separate resistor"), and in the description of the embodiments shown in FIGS. 3 and 4 in which each conductive segment has a connector link that connects the conductive segment to a connecting tab, page 6, line 17 to page 7, line 22. It is an unwarranted distortion of the '642 patent to suggest that any conductive segment not be attached to a connecting tab. Indeed, one would have modify the electrodes of the '642 patent in a way that departs from the consistent teachings of the '642 patent to arrive at the characterization made of the '642 patent in the office action.

All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patents issuing thereon.

Signed:

Burrhus Lang

Date: December 14, 2006

NUMERICAL FIELD CALCULATION OF PATIENT RETURN ELECTRODES IN ELECTROSURGERY

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Abstract— In order to examine the warming up caracteristics during application of a new electrode design for a patient return electrode of an electrosurgical system numerical field calculations were performed in this study. A multi-layer thigh model was provided for this purpose, to which the patient return electrode and the active electrode were connected. The simulation geometry as well as the dielectric tissue parameters were set according to the current frequency. The heating up at the skin surface by the flowing current was evaluated. The results were compared with experimental thermographical measurements.

Keywords—*numerical field calculation, multi-layer thigh model, patient return electrode, thermography*

Introduction

During monopolar high-frequency (HF) electrosurgery a patient return electrode with a large contact area must be applied to the patient's skin to establish a closed electric circuit. To prevent tissue damage due to thermal heating of the return electrode induced by the current flow safety issues, such as low current densities and small transition resistances, must be strictly observed – as demanded in standards like the AAMI HF-18 [1].
The idea of a new electrode design with a circumferential neutral ring ("equipotential ring") emerged from several requirements, including a relatively small total electrode area to be able to apply the electrode to the extremities of both, adults and children, without problems. The optimal geometric shape was determined from several different return electrode designs using thermography.
By means of numerical simulations the advantageous effects of the new design have successfully been proven. Furthermore the numerical simulations enabled us to gain fundamental knowlegde for further design improvements.

Materials and Methods

In order to realize a new electrode design with an equipotential ring the standards of the American National Standard AAMI HF-18 § 4.2.3.1 [1] must be taken thoroughly into account. These standards stipulate a test procedure in which the concerned return electrode must be affixed to the skin of a test person. Then a sinusoidal current (700 mA) of an electrosurgery unit (ESU) is applied to the test person in-vivo for 60 s (cf. fig. 1).

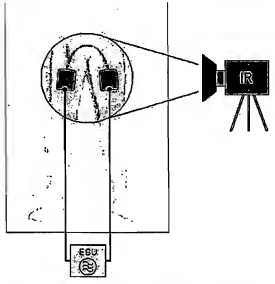


Figure 1: Diagram of the experimental setup for the safety test procedure according AAMI-standards [1]. A test person is connected to an electrosurgical unit (ESU) via two return electrodes. After the application of the test current the heating of the skin is measured using infrared (IR) thermography.

Using a suitable measurement method (in this case infrared (IR) thermography) the surface temperature of the skin is determined after peeling off the return electrode (cf. fig. 2). When using this method it is essential to ensure a minimum area of resolution of 1 cm² of the IR-camera according to [1]. In this test the maxmimum temperature rise on the thigh-surface must not exceed a limit of 6 K above the skin temperature at the beginning of the test procedure. The return electrode presented in this paper successfully passed the described test procedure.
Experimental results showed significant differences between different return electrode designs. In order to study these phenomena a multi-layer tissue model of the human thigh was designed for numerical simulations according to available anatomical data of the human body [3,4]. This model consists of a multi-layer cuboid tissue brick (cf. fig. 3) built up of different tissue types and materials. The base brick consists of skin, fat and muscle tissue where the thickness of the fat-layer was varied to simulate obese or slim test persons (cf. tab. 1). The thickness of the

remaining layers was set at an average value for humans (skin 2 mm, muscle 70 mm) [3,4]. The appropriate dielectric parameters for the different tissue types (according to the output frequency of the ESU) were taken from the tables of Gabriel [2].
A hydrogel layer was simulated between the return electrode (material: aluminum) and the skin surface in order to represent the clinical application properly. The dielectric parameters of this gel were experimentally determined prior to the numerical simulations.
The geometry of the return electrode was exactly remodelled for the numerical simulations on the basis of CAD-datasets. The modell was transformed into a 3D-mesh containing more than 800 000 cuboid voxels. The mesh resolution was varied to ensure a satisfactory approximation of the geometric specifications of the return electrode, thus facilitating numerical convergence of the solving algorithm.

The active electrode which injects the current into the thigh model was placed 200 mm away from the return electrode model (cf. fig. 3). For a worst-case assessment the return electrode was placed perpendicularly to the symmetry line, to allow an asymmetric current flow towards the return electrode, thus being most likely to produce maximum heating effects (as already proven by experiment). The peak value of the current was set at 1.41 A which corresponds to a rms-value of 1 A. The frequency was set at 350 kHz. The return electrode was connected to the active electrode via a filament, closing the electric circuit. To ensure numerical accuracy the total current flow through the model was evaluated using Ampère's law, calculating the line integral of the magnetic field along several closed integration paths around the model. The demanded current flow through the model and especially the hydrogel-layer could be guaranteed via this procedure.

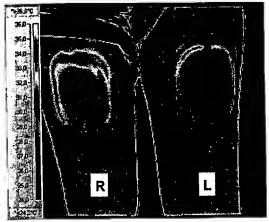


Figure 2: IR-thermography of a test person showing the local heating of the skin comparing two diffent electrode designs. The right thigh shows a conventional electrode without equipotential ring resulting in significantly higher heating of the skin than when using the return electrode with equipotential ring placed on the left thigh.

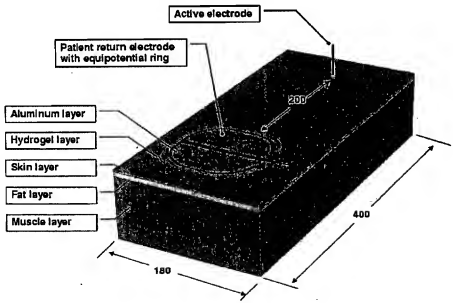


Figure 3: Setup of the numerical thigh model. The model consists of a three-layer tissue block. The tissue types are skin, fat and muscle. The figure shows the placement of the return electrode, as well as the application of the active electrode simulating the electrosurgical instrument. A hydrogel layer, acting as a contact agent, between skin and electrode was also considered to represent the clinical application as closely as possible. The active electrode and the return electrode are connected via a filament to close the electric circuit. All dimensions of the drawing are in mm.

By varying the given parameters (cf. tab. 1) eight different tissue models were set up. One parameter was the variation of the return electrode geometry. This allowed to study the effects of the equipotential ring (experimental results show a positive effect in respect to heating of the skin using return electrodes with equipotential rings). Furthermore the thickness of the fat-layer and the skin type were varied. To investigate the influence of a single parameter, calculations were performed in pairs while changing one of the significant parameters.

Simulations no. 1 and no. 2 compare the influence of the equipotential ring in a test person with dry skin, while no. 3 and no. 4 do the same for wet skin. No. 5 and no. 6 study the impact of the fat-layer in a mixed skin type (averaged values of dry and wet skin). No. 7 and no. 8 show the differences between dry and wet skin assuming a very thick fat-layer (20 mm).

The solving process for the numerical problem can be split into two different parts. First the electromagnetic problem must be solved to calculate the current flow through the tissue model. Using these values the energy absorbed in the tissue can be calculated. In a second step the calculated power loss can be used as an input parameter for solving the thermodynamic problem considering heat transfer processes, leading to a more realistic simulation.

Table 1: Parameters of the different models. In this study the thickness of the fat layer, the skin type (dry/wet) and the electrode design were varied.

No.	Skin (mm)	Fat (mm)	Muscle (mm)	Skin Type	Neutral Ring
1	2	12	70	Dry	Yes
2	2	12	70	Dry	No
3	2	12	70	Wet	Yes
4	2	12	70	Wet	No
5	2	20	70	Mix	Yes
6	2	0	70	Mix	Yes
7	2	20	70	Dry	Yes
8	2	20	70	Wet	Yes

Table 2: Specific heat capacity c_s, density ρ, permittivity ε_r and conductivity σ of the different materials used in the numercial simulations. For aluminum an ideal electric conductor was assumed.

Material	c_s (J/kg*K)	ρ (kg/m³)	ε_r ()	σ (S/m)
Aluminum	896	2702	1	∞
Hydrogel	4182	1010	1350	0.1500
Skin Dry	3663	1010	1083	0.0025
Skin Wet	3663	1010	5160	0.1565
Fat	2973	920	62	0.0437
Muscle	3639	1040	4755	0.4177

As a worst case estimation however the solution of the electromagnetic problem can be used to calculate the energy deposition in the tissue by evaluating the electrical field (Joule losses). Hence follows, taking the specific heat and the tissue density (cf. tab. 2) into account, a simple formula for a worst case assessment of the expected maximum heating of the tissue:

$$\Delta T = \frac{(\sigma + \omega\varepsilon_0\varepsilon_r)\cdot E^2}{2c_s\rho} \qquad (K/s) \qquad (1)$$

σ	conductivity	(S/m)
ω	angular frequency	(1/s)
ε_0	electrical field constant	(F/m)
ε_r	permittivity	()
E	electrical field	(V/m)
c_s	specific heat	(J/kg*K)
ρ	density	(kg/m³)

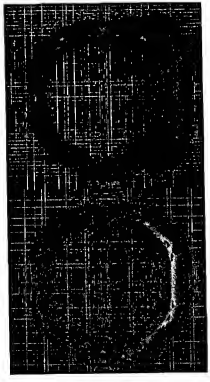
The worst case assessment implies that no heat transfer takes place at all. All deposited energy is stored locally and transformed into heat. However calculation of the heating by solving the thermodynamic problems yield more accurate results which are significantly lower than those calculated with formula (1).

Results

According to the experimental results, return electrodes with an equipotential ring are shown to produce significantly less heating at the skin surface during application of electrosurgery. A direct comparison (cf. fig. 4) yields a higher heating of the electrode without an equipotential ring on wet skin. Furthermore a characteristic asymmetrical heating pattern can be observed using electrodes without equipotential rings.

Assuming an initial skin surface temperature of 305 K the worst case assessment yields a maximum heating of the skin surface after 60 s of up to 326.3 K without the ring and up to 319.7 K with the equipotential ring. Solving the thermodynamic problem yields a maximum heating of up to 319.9 K without the ring and of up to 315.2 K with an equipotential ring. As expected these values are significantly smaller than assessed in the worst case with the equation (1).

Another interesting result was observed while comparing the effects of wet and dry skin with a 20 mm fat-layer (cf. fig. 5). The model with wet skin showed ten times more heating than the model with dry skin. This is due to higher Joule losses in the wet skin as the conductivity is more than a factor of 60 better than in the case of dry skin. This yields a higher deposited power in the wet skin since only the effective power significantly contributes to the heating effects in a low HF-frequency range. The dry skin layer is assumed to transport the energy as a capacitor, producing mostly reactive power which yields less heating of the skin surface.



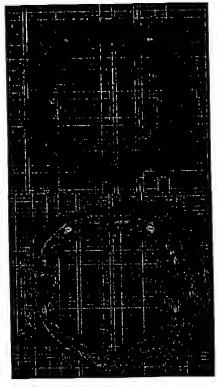
305K 320K

Figure 4: Heating of the skin surface (wet skin, 12 mm fat-layer) after continuous application of an electrical current (peak value 1.41 A) for 60 s, considering heat transfer mechanisms. The return electrode without an equipotential ring shows asymmetric heating and hot spots (lower image). The electrode with an equipotential ring shows less heating and a homogeneous heat distribution (upper image). For better comparison the scaling of the colorbar in both images is identical (range: 305 K to 320 K)

However the impact of the hydrogel layer must not be neglected. As the numerical calculations show, most of the effective power is directly deposited at the electrode-hydrogel transition, especially at the edge of the electrode. The electrode edges lead to a distortion of the electric field and furthermore to a concentration of the electric flux lines, hence resulting in a larger heating at the electrode edges.

Discussion

The results of the numerical calculations are in agreement with the obtained experimental results. The use of numerical techniques yielded a validation of the experimental results and a better understanding of the heating effects. Altogether return electrodes with equipotential rings have proven to be advantageous in comparison with conventional electrodes regarding heating effects of the patients' skin, since significantly less heating occurs during electrosurgery.



305K 325K

Figure 5: Heating of the skin surface (dry/wet skin, 20 mm fat-layer) after 60 s considering heat transfer mechanisms. The effects of dry and wet skin are compared. Wet skin (lower image) shows significantly higher heating than dry skin (colorbar range: 305 K to 325 K).

Return electrodes with equipotential ring also showed a widely homogeneous and symmetric heating pattern with no hot-spots. As observed, numerical simulation techniques can be used to validate the effects of new electrode designs and furthermore for numerical studies prior to expensive and time consuming experiments to ensure patient safety.

Another relevant problem is the impact of blood vessels near the skin surface and hence the formation of hot spots. This will be included in numerical studies in the future.

References

[1] Association for the Advancement of Medical Instrumentation, ANSI/AAMI HF-18, http://www.aami.org, Edition 2001

[2] Gabriel et al., *« Compilation of the Dielectric Properties of Body Tissues at RF and Microwave Frequencies »*, http://www.brooks.af.mil/AFRL/HED/hedr/reports/dielectric/Title/Title.html, 1999

[3] H. Frick et al., *Allgemeine Anatomie – Spezielle Anatomie I*, Thieme

[4] De Graaf et al., *Concepts of Human Anatomy and Physiology*, wcb Wm. C. Brown Publishers

APPENDIX - Related Proceedings

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